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शिशु सेने का यंत्र — विशिष्टि

(दूसरा पुनरीक्षण)

Indian Standard

BABY INCUBATORS — SPECIFICATION

(Second Revision)

ICS 11.040.30

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 2

Hospital Equipment Sectional Committee, MHD 14

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Hospital Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1965 and was subsequently revised in 1978. The second revision of this standard is brought out keeping in view the latest developments in the manufacture of electrically heated baby incubators. In this revision reference has been made to IS 13812 (Part 19) 1994 'Medical electrical equipment — Particular requirements for safety: Part 19 Baby incubators'. This revision also takes into account the three amendments issued to this standard from time to time.

This standard covers the performance, safety and general requirements for electrically heated incubators for prematurely born babies, with a view to providing a comfortable, safe and convenient method of maintaining the baby at a temperature and humidity decided by medical authorities.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

BABY INCUBATORS — SPECIFICATION

(Second Revision)

1 SCOPE

This standard lays down requirements for electrically heated incubators for use in hospitals for keeping prematurely born babies at a predetermined temperature and humidity.

2 REFERENCES

The Indian Standard IS 13812 (Part 19) : 1994 'Medical electrical equipment — Particular requirements for safety: Part 19 Baby incubators' contains provisions which through reference in this text, constitutes provision of this standard. At the time of publication, the edition indicated above was valid. The standard is subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard.

3 TERMINOLOGY

3.1 Incubator

A closed chamber designed and constructed for the treatment of prematurely born babies; and incorporating a built-in means of heating and humidifying the air and of oxygen supply to the chamber.

3.2 Incubator Temperature

The mean of the temperatures of air at the centre of the working space at a cut-in of the thermostat and at the cut-out immediately following.

3.3 Temperature Variation

The difference in the temperature of air at the centre of the working space and at any other point in the working space at any instant.

3.4 Temperature Differential

The cyclic change of temperature at any point, regulated by the operation of the thermostat.

3.5 Temperature Drift

The change in incubator temperature which may take place in continuous operation over a long period.

3.6 Temperature Overshoot

The amount by which the maximum temperature attained by air at the centre of the working space during the initial heating up, exceeds the incubator temperature when steady operating condition of the thermostat is reached.

3.7 Rated Voltage

The voltage specified on the name plate. It can be either a single voltage or range of voltages, for example, 230 to 250 volts.

3.8 Maximum Rated Voltage

Where a voltage range is marked on the name plate, the highest value of that range. Where only a single voltage is marked the maximum rated voltage is the rated voltage.

3.9 Maximum Rated Loading

The power consumed by the appliance when all electrical components are connected to a supply at the maximum rated voltage.

4 RATING

4.1 Voltage Rating

The rated voltage shall be as follows:

a) ac 240 V 50 Hz, and
b) dc 240 V, *Max.*

5 MATERIALS

5.1 The provisions of IS 13812 (Part 19) shall apply.

5.2 Only non-ignitable and non-hygroscopic materials shall be used.

5.3 Materials shall be non-corrodible or have a surface finish which adequately protects against corrosion at the temperature and humidity to which they will be normally subjected. Any finish on the surfaces of the baby compartment shall be non-ignitable. Flammable finishes shall not be used on other surfaces.

5.4 The hood of the baby incubator may be made from acrylic monomer sheet having a minimum thickness of 6 mm.

6 CONSTRUCTION

6.1 The relevant provisions of Sections 4 and 10 of IS 13812 (Part 19) shall apply.

6.2 Incubators shall be made of good quality impermeable materials, and the construction shall be robust and workmanlike throughout. The internal surfaces forming the baby compartment shall be smooth and free from unsealed formations which may harbour dirt or foreign matter and all corners shall be rounded. The lids shall be so designed that they cannot fall abruptly.

6.3 The baby incubators shall preferably be fitted with castors with conductive (antistatic) rubber tyres. If castors with non-conductive tyres are fitted, the body of the baby incubator shall be earthed by means of the chain hanging on to the floor.

6.4 When agreed to between the purchaser and the supplier, baby incubators shall incorporate facilities to nurse the baby by means of suitable openings in front or top of the incubator. The openings shall provide air-tight seal round the nurses' hand, so that the temperature or humidity inside the incubator is not disturbed.

6.5 Special attention shall be given to the elimination of vibration and noise from any moving parts of electrical components connected to alternating current.

6.6 All electrical components except the audible alarm device specified in **6.14** and **6.15**, and all electric wiring other than the flexible cable connection to the electricity supply, shall be incorporated within an outer casing which provides effective protection against mechanical damage and from water or other surface is mopped or cleaned.

6.7 The incubator shall have transparent walls at least in front and top. When glass is used, it shall be of toughened type.

6.8 Suitable ventilators shall be provided for infiltration of fresh air inside the incubator. The ventilators shall be such that when oxygen is administered separately, they can be closed.

6.8.1 The floor of the incubator on which the baby has to be kept shall have a rubber foam or polyurethane foam mattress not less than 25 mm thick and having a suitable cotton cloth cover. The floor shall be equipped with tilting arrangement.

6.8.2 *Humidifier*

A humidifier unit incorporated shall:

a) be made of stainless steel;
b) be capable of attaining the relative humidity over the operating temperature range not less than 65 percent;
c) have a water level indicator where the level of the water in the tank cannot be seen and an overflow pipe arranged so that water is not spilt inside the apparatus in the event of over filling;
d) have the water tank enclosed and partitioned as is necessary to prevent water spillage from the tank when the apparatus is tilted 10° out of the horizontal in any direction; and
e) have the electrical components positioned so as to reduce the possibility of damage from water in the event of spillage or leakage from the water tank.

6.8.2.1 A sensitive hygrometer shall be suitably fixed inside the incubator.

6.9 Heating Elements

Heating elements shall be of a totally enclosed metal clad type and shall be located or protected to prevent the possibility of persons using the appliances coming into contact with them. Incubators may also be heated by means of electric lamps.

6.9.1 The exposed surfaces protecting heating elements located inside the baby compartment shall not be operated at temperatures exceeding 93°C and those located outside the baby compartment shall not be operated at temperature exceeding 120°C.

6.9.2 The heaters shall be arranged to provide uniform heating throughout the baby compartment and to eliminate the possibility of excessively hot surfaces. No surfaces accessible to the baby shall reach a temperature exceeding 40°C.

6.10 Temperature

6.10.1 *Maximum Temperature*

The maximum temperature in the baby compartment when the thermostat is adjusted to the highest temperature setting,when measured as described in **10.5.2**, shall not exceed 35°C (98°F).

6.10.2 *Temperature Variation*

At any temperature setting the variation in temperature from head to foot of baby compartment shall not vary more than ±0.5°C.

6.10.3 *Temperature Differential*

The temperature differential of baby mattress from head to foot when measured as described in **10.5** shall not vary more than ±0.5°C.

6.10.4 *Temperature Overshoot*

The temperature overshoot when tested as described in **10.7** shall not vary by more than ±0.5°C.

6.11 Thermometer

A thermometer having an accuracy of 0.25°C shall be provided on the incubator. The bulb capacity of the thermometer shall not be greater than 0.5 ml.

6.12 Electrical Wiring

The wiring and connections of heating element shall be so arranged that they are separated from the baby compartment and also from each other and from oxygen duct which is connected to the baby compartment, by non-ignitable barriers. The terminals shall be such that they do not slacken or overheat during normal use.

6.13 Oxygen Supply

Where oxygen cylinders are used on the incubator, a reducing valve shall be provided to reduce the working pressure.

A pressure gauge shall be provided on the high pressure side of the valve. An oxygen flow meter shall be provided on the low pressure side of the reducing valve.

6.14 High Temperature Alarm

Audible and visual means shall be incorporated to give warning of the operation of the high temperature cut-out. The visual warning shall consist of a light coloured red and having a rating of at least five watts. The audible alarm shall consist of a bell or equivalent device permanently attached to the outside of the incubator or mounted in a well ventilated compartment so as to be clearly audible. A test switch shall be incorporated to enable the alarm circuit to be tested. It is preferable for this switch to be of the push 'ON' type with a spring operated return to the 'OFF' position. If desired, provision may be made for an additional audible alarm which may be located away from the appliance, for example, a parallel circuit consisting of a plug and socket and bell attached to flexible cable. Provisions given in IS 13812 (Part 19) shall be followed.

NOTE — It is recommended that the alarm circuits including any remote alarm operate at a potential not exceeding 8 volts.

6.15 Electric Supply Failure Alarm

Audible means shall be incorporated to give warning of a failure of the electric supply. A bell or similar audible alarm provided for this purpose shall be battery operated, and the alarm circuit shall be arranged so that it is switched 'ON' and 'OFF' with the main supply to the appliance.

NOTE — If desired, the audible alarm required in **6.14** may also be used as a heater failure alarm and be controlled by a no-volt relay, incorporated in the heater circuit or in the supply line to the heater circuit.

6.16 Indicator Lamp

The incubator shall be incorporated with two indicator lamps, one of amber colour to indicate that the electric supply is 'ON' and another of blue colour to indicate that the heating circuit is 'ON'. These indicator lamps are additional to the red warning light required for high temperature alarm, as specified in **6.14**.

6.17 Electric Motor

Electric fans when used shall have motors of the totally enclosed type.

7 GENERAL AND SAFETY REQUIREMENTS

7.1 For general and safety requirements like protection against electric shock, electric insulation, stability, mechanical strength, supply connections, terminals, earthing, screws and connections and resistance to rusting of the incubator the provisions given in IS 13812 (Part 19) shall apply.

8 PERFORMANCE REQUIREMENTS

8.1 The incubators, when switched on at ambient temperature shall take not more than 45 minutes to attain the temperature of 32°C in the baby compartment (*see also* **10.4**).

8.2 Temperature Variation

The incubators shall satisfactorily pass the tests specified in **10.4**.

9 MARKING AND INSTRUCTIONS FOR USE

9.1 Each incubator shall be marked indelibly and clearly on its outer surface or on a name plate firmly attached to it. A prominent label shall be fixed on the baby incubator with inscription:

'No Naked Flame, No Smoking' or pictorially.

The controlling knobs shall be suitably inscribed to indicate their purpose.

9.2 BIS Certification Marking

The incubators may also be marked with the Standard Mark.

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

9.3 Marking of Earth Terminal

The symbol '⏚' shall be marked permanently on or adjancent to the earth terminal, if provided.

9.4 Instructions for Use

Each incubator shall be provided with necessary instructions including precautions to be taken for its proper use.

10 TESTS

10.1 General Conditions of Tests

10.1.1 *Test Voltage*

The tests shall be carried out either at the rated voltage or at the maximum voltage of the range unless otherwise specified in the relevant clauses. The test voltage shall not vary by more than ±10 percent during the test.

10.1.2 *Ambient Temperature*

The ambient temperature during the performance tests shall be 27 ± 2°C.

10.2 Visual Examination and Inspection

The incubators shall be examined and inspected for general construction and marking requirements.

10.3 Mechanical Strength

Test for mechanical strength, protection against electric shock, high voltage, insulation resistance, leakage current, earthing connection and input shall be conducted as given in IS 13812 (Part 19).

10.4 Variations of Temperature

Five thermometers complying with **6.11** or five temperature sensing elements of a suitable recording thermometer shall be located on the surface of baby mattress in the baby compartment. One shall be located in the centre of the baby mattress and other four on four corners within 1 cm of the corner edge. When steady temperature conditions have been reached, temperature difference between the reading of the central element of thermometer and those at each of the other four locations shall be noted and shall not exceed ±0.5°C.

10.4.1 The appliances shall be allowed to cool to room temperature and the rest shall be repeated with the temperature controlling device adjusted at the maximum temperature setting.

10.5 Temperature Differential Test

In this test a thermometer complying with **6.11** or a temperature sensing element with a suitable recording thermometer shall be used and be located in normal position occupied by the thermometer in the baby compartment of an incubator and calibrated to the reading of temperature with the centre of the top surface of the mattress in the baby compartment. The appliance shall be operated with the temperature setting of approximately 33°C in the baby compartment. When steady temperature condition has been reached the temperature shall be recorded at intervals of not more than 2 minutes for 40 minutes. The temperature reading shall not vary by more than 0.5°C.

10.5.1 The appliances shall continue to operate at the same setting for four hours. At the end of this period the temperature shall be again be recorded at intervals of not more than two minutes for 40 minutes and again the temperature readings shall neither vary by more than ±0.5°C nor differ by more than ±0.5°C from any of the earlier readings.

10.5.2 The test shall be repeated with the temperature controlling device adjusted at the maximum temperature setting. The maximum temperature recorded shall not be greater than 35°C.

10.6 Temperature Drift Test

With the incubator adjusted as required in **6.10.2** the temperature shall be recorded once in six hours with the thermometer complying with the requirements specified in **6.11** over the thermometer complying with the requirements specified in **6.11** over a continuous period of 72 hours. The temperature drift measured shall not exceed ±0.5°C.

10.7 Temperature Overshoot Test

For this test a thermometer is used as described in **10.5**. The thermostat shall be adjusted to obtain a temperature of approximately 29.5°C (85°F) in the baby compartment and the appliance operated until steady temperature conditions are reached. The maximum temperature indicated during the heating-up period shall not exceed the maximum temperature indicated after steady temperature conditions are reached by more than ±0.5°C.

10.7.1 The appliance shall be allowed to cool to room temperature and the test repeated with the temperature controlling device adjusted at the maximum temperature setting.

10.7.2 This test may be carried out in conjunction with the temperature differential test described in **10.5**.

10.8 Test for Reproducibility of Temperature Setting

The temperature controlling device shall be adjusted to obtain a temperature of approximately 32°C (89.6°F) in the baby compartment and after steady temperature conditions have been reached the maximum temperature reading of the thermometer shall be noted. The appliance shall be allowed to cool for at least six hours and the test repeated without any alteration of the thermostat setting. The original temperature shall be regained to within 1°C.

10.8.1 The test shall be repeated with the temperature controlling device adjusted at the maximum temperature setting.

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